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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,478	02/25/2004	Jingcai Chen	PRD2045NP-US	1497

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,478	CHEN ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 30 April 2007 has been entered in full. Claims 2, 4-6, 8, and 10-30 have been cancelled and claim 1 has been amended.

Claims 1, 3, 7, and 9 are pending and under examination.

35 USC § 112, Second paragraph

Applicant's amendments to claim 1 and the cancellation of claim 6 in the response filed on 04/30/2007 have overcome the rejection of claims 1-10 under 35 U.S.C. § 112, second paragraph. The rejection of claims 1-10 under 35 U.S.C. § 112, second paragraph has been withdrawn.

35 USC § 112, First paragraph (written description)

Applicant's response and arguments filed on 04/30/2007 have overcome the rejection of claims 1-10 under 35 U.S.C. § 112, first paragraph (written description). The rejection of claims 1-10 under 35 U.S.C. § 112, first paragraph (written description) has been withdrawn.

35 USC § 112, First paragraph (enablement)

Applicant's response and arguments filed on 04/30/2007 have overcome the rejection of claims 1-10 under 35 U.S.C. § 112, first paragraph (enablement). The rejection of claims 1-10 under 35 U.S.C. § 112, first paragraph (enablement) has been withdrawn.

35 USC § 102

Applicant's response, arguments, claim amendments, and the cancellation of claims 2,

4-6, 8, and 10 filed on 04/30/2007 (see page 4) have overcome the rejection of claims 1, 2, 5-8, and 9-10 under 35 U.S.C. § 102(b). The Examiner agrees with Applicant that the receptor LGR7 disclosed in Sudo et al. (2002) is a different receptor from the GPCR135 that is claimed in the instant application. The rejection of claims 1, 2, 5-8, and 9-10 under 35 U.S.C. § 102(b) has been withdrawn.

35 USC § 103

Applicant's response, arguments, claim amendments, and the cancellation of claim 4 filed on 04/30/2007 (see page 4) have overcome the rejection of claims 1, 3, and 4 under 35 U.S.C. § 103(a). The Examiner agrees with Applicant that the receptor LGR7 disclosed in Sudo et al. (2002) is not the GPCR135 that is claimed in the instant application. The rejection of claims 1, 3, and 4 under 35 U.S.C. § 103(a) has been withdrawn.

Rejections Maintained

Double patenting

Claims 1, 3, 7, and 9 of the instant application are in conflict with claims 1-10 of Application No. 10/547,875. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. The basis of this rejection is set forth for claims 1-10 at page 3 of the previous Office action mailed 11/29/2007.

The rejection of claims 1, 3, 7, and 9 is maintained. Applicant's response, arguments filed on 04/30/2007 have been fully considered but they are not persuasive.

At page 3 of the response filed 04/30/2007, Applicant requests that the this provisional double patenting rejecting be held in abeyance, as Applicant intends to cancel claims 1-10 from the co-pending application in due course.

Applicant's arguments have been fully considered and the Examiner will maintain this rejection until Applicant cancels claims 1-10 from the co-pending application.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 7, and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The basis of this rejection is set forth for claims 1-10 at page 3 of the previous Office action mailed 11/29/2007.

The rejection of claims 1, 3, 7, and 9 under 35 U.S.C. § 101 & § 112, First paragraph is maintained. Applicant's response, arguments filed on 04/30/2007 have been fully considered but they are not persuasive.

At page 3 of the response filed 04/30/2007, Applicant argues that the specification describes the claimed receptor-ligand complex as having utility in assay methods for identifying compounds that modulate the biological activity of the complex. In addition, although the inventive complex is useful to identify drug candidates for treating more than one particular disease or disorder, the utility as a drug screening material is nonetheless specific.

In addition, Applicant argues the utility is substantial as reflected by the investments of pharmaceutical companies in developing and performing drug screening assays targeting GPCRs, the claimed invention has a practical, real world value. Furthermore, Applicant argues that the asserted utility is credible because the Examiner has failed to satisfy the USPTO's burden of establishing that one of ordinary skill in the art would doubt that the inventive complex had the asserted utility.

Applicant's response and arguments have been fully considered but are not found persuasive. The truth, or credibility, of the assertion of utility has not been questioned. Rather, the rejection sets forth that the assertion of utility is not specific or substantial. The Examiner acknowledges that "[in] most cases, an Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101 (MPEP § 2107.02 (section III)). However, in the previous Office Actions of 29 November 2006, the Examiner made a *prima facie* showing that the claimed invention lacks utility and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing.

Essentially, Applicant has not provided evidence to demonstrate that the claimed human G protein-coupled receptor 135 (GPCR135) of the instant application is supported by a specific and substantial asserted utility or a well-established utility. The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response (see below). It is noted to Applicant that MPEP § 2107.02 (part VI) also states that "only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained".

The specification of the instant application discloses that the human G protein-coupled receptor 135 (GPCR135) in the instant application is a novel receptor protein that is expressed in human cells. The specification teaches that GPCR135 is an orphan receptor that has been found to be expressed almost exclusively in the central nervous system (page 2, last paragraph). In addition, the specification discloses that the putative amino acid sequence of GPCR135 suggests that its ligand is peptidergic in nature (page 2, 3rd paragraph). However, the instant specification does not teach any functional characteristics of the GPCR135 polypeptide. The specification does not disclose the polypeptide in the context of a cell or organism or any methods or working examples that indicate the polypeptide of the instant invention is involved in any activities. Since significant further research would be required of the skilled artisan to determine how the GPCR135 polypeptide of amino acid SEQ ID NOs:12, 13, or 15 is involved any activity, the asserted utilities are not substantial.

Additionally, G protein-coupled receptors (GPCRs) and signaling molecules are extremely diverse, as evidenced by Ji et al. (J Biol Chem 273(28): 17299-17302, 1998) and by Applicant in the specification (page 2, 2nd paragraph), and each new GPCR/signaling molecule needs to be evaluated empirically to determine the precise role(s) it plays. Since the utility is not presented in mature form and significant further research is required, the utility is not

substantial.

Although the instant specification asserts that the identification, selection, and validation of novel molecular targets for drug discovery is a patentable utility (pg 1, 2nd paragraph and pg 2, 2nd paragraph) ,this asserted utility is not specific or substantial. Such assays can be performed with any polypeptide. Nothing is disclosed about how the polypeptide is affected by the ligand. Additionally, the specification discloses nothing specific or substantial for the molecular targets that can be identified/selected/validated by this method. The specification does not provide a nexus between the GPCR135/relaxin complex and any disease or disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Additionally, commercial success is not necessarily evidence of patentable utility. Commercial success requires more than the mere sale of a compound. Commercial success is discussed in the MPEP at 716.03 and appears to be applicable to obviousness rejections, but does not appear to be a valid consideration for utility which requires specific, substantial and credible utility.. Applicant also has not established a nexus between the *claimed* invention and evidence of commercial success. The sale of a compound is not evidence of commercial success and sale of a compound for use as a scientific tool does not appear to be a specific, substantial and credible utility as set forth in the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS".

Claims 1, 3, 7, and 9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, credible utility, asserted utility or a well established utility for the reasons set forth above, one skilled in the art

clearly would not know how to use the claimed invention. The basis for this rejection is set forth at page 8 of the previous Office Action mailed 11/29/2007.

Since Applicant has not provided evidence to demonstrate that the GPCR135/relaxin complex have a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. It is noted that the instant specification is required to teach one skilled in the art how to make and use the claimed polypeptide.

New Ground of Rejection

Claim Rejections - 35 USC § 112 (Second paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 7, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 7, and 9 are rejected as being indefinite because it is not clear if GPCR135 can be complexed and have an activity with relaxin3 from other species. For example, it is not clear if the claim is intending to encompass the complex of human GPCR135 of SEQ ID NO: 12 with human relaxin3 OR human GPCR135 of SEQ ID NO: 12 with mouse relaxin3.

Claim 1, 3, 7 and 9 are indefinite because the elements recited in the claim do not constitute proper Markush groups. The claims are indefinite because it is not clear what controls which of these limitations. (See especially claim 1) See MPEP § 2173.05(h). Please note that Applicant can overcome the rejection by amending claim 1 with the following phrase: "selected from the group consisting of SEQ ID NO:12, SEQ ID NO:13, and SEQ ID NO:15".

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
July 20, 2007

Bridget E. Bunner

BRIDGET E. BUNNER
PRIMARY EXAMINER